

REMARKS:

In response to the Office Action mailed August 2, 2006, claims 17-20, and 75 have been canceled without prejudice, claims 1, 21, 74, 92, 98-100, 108, and 115 have been amended, and claims 32, 37, 96, 113, 116, and 117 have been rewritten in independent form. The status of claims 22, 28, and 75 have been changed to “withdrawn” to correspond to the Examiner’s analysis of Applicants’ May 22, 2006 election. In addition, formal drawings are filed herewith, and the specification has been amended to correct obvious typographical errors.

In the Office Action, the drawings and the specification were objected to, and claims 51-53, 74, 93, and 98-100 were objected to for informalities. In addition, claims 74 and 101 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, and claims 17-21 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Finally, claims 1, 2, 9, 10, 15-21, 24, 29, 34, 41, 51-54, 56, 92-95, 97-112, and 114-115 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,241,765 (“the Griffin et al. reference”) and claims 1, 2, 9, 10, 14-21, 24, 29-31, 34, and 41 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Publication No. 2003/ 0109922 (“the Peterson et al. reference”).

Because neither of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

First, Applicants appreciate the Examiner’s indication that claims 32, 37-39, 96, 113, and 116-118 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim. Claims 32, 37, 96, 113, 116, and 117 have been

rewritten in independent form, and therefore should now be allowable, as should dependent claims 38, 39, and 118.

In the Office Action, the Examiner also requested additional information, namely support for claim amendments and a list of co-pending applications that set forth similar subject matter to the present claims. Applicants have filed several applications that are co-pending that relate to the subject matter of the present application, e.g., disclosing and/or claiming multiple component heart valve assemblies and/or gasket members, including Serial Nos. 10/327,821, 10/355,429, 10/765,725, 11/069,081, 11/144,254, 11/069,457, 11/069,617, 11/080,009, 11/279,246, and 11/420,720.

With respect to support for any amendments to the claims, amendments to original claims, e.g., claims 1 and 75, may be found throughout the specification and drawings, e.g., between page 19, line 5 and page 22, line 6, and in FIGS. 25 and 26. In addition, the current amendments to claim 1 are supported, e.g., by original claim 37, at page 29, lines 9-21, and in FIGS. 49 and 50. Support for new claims 92-118 may be found in the original claims, and throughout the specification and drawings, e.g., at page 15, lines 7-23, between page 17, line 8 and page 22, line 6, at page 29, lines 9-21, between page 41, line 22 and page 42, line 4, and between page 50, line 21 and page 51, line 23, and in FIGS. 23-26, 49-55, 88-90, and 128-130. In addition, the current amendments to claims 92 and 108 are supported, e.g., at page 29, lines 9-21, between page 41, line 22 and page 42, line 4, and in FIGS. 49-55, 89, and 90.

Turning to the objections to the drawings, formal drawings are filed concurrently herewith. The new drawings include drawings replacing FIGS. 1-3, which include the legend "PRIOR ART," as requested by the Examiner. In addition, FIGS. 29 and 34 have been amended

to correct obvious typographical errors, i.e., replacing the lower “60” with “62” in FIG. 29 and replacing the lower “60” with “114” in FIG. 34. No new matter has been introduced as the amendments are fully supported by the original specification, e.g., at page 18, line 3, and page 25, lines 9-15, respectively.

With respect to the objections to the specification, the term “shelves” and “slopes” are used in paragraph 0149 of the specification (page 29, line 11) in conjunction with FIGS. 49 and 50 to describe features of teeth internal to the can, e.g., that cooperate with corresponding features on sutures. This species was elected in Species Set 1. Thus, the terms “shelf” and “slope” used in the claims merely recite one of these shelves and slopes, and therefore are properly supported by the original specification. Accordingly, this objection should be withdrawn.

Turning to the claim objections, the preambles of claims 1, 74, and 92 have been amended to recite “A heart valve device for connection to a first mass.” Thus, as originally intended, the preambles do not positively recite a heart valve, but rather a heart valve device. Claims 98-100 have been amended to positively recite a “heart valve.” Accordingly, these objections should be withdrawn.

Turning to the rejections under § 112, first paragraph, claim 74 recites “a gasket body comprising an annular wall covered by fabric” and claim 101 recites that “the annular body is covered by fabric.” These limitations are fully supported by the original specification and drawings, for example, between page 21, line 1 and page 22, line 6, and in FIGS. 25 and 26. FIG. 26 is a cross-sectional view of FIG. 25 taken along line B-B, and clearly shows an annular wall 52 that is covered by a sewing ring 14 that can be fabric. See, page 21, lines 1-3. With

respect to the rejections under § 112, second paragraph, claims 17, 18, and 20 have been canceled without prejudice, and claims 19 and 21 have been amended to recite the sewing ring rather than the flange. Accordingly, these rejections should be withdrawn.

Turning to the § 102(b) rejections, the Griffin et al. reference discloses a prosthetic heart valve 10 that includes an annular valve body 14 with pivoting leaflets 16, 18, and a stiffening ring 29. Col. 2, lines 59-61. The stiffening ring 29 includes a shoulder 57 that includes recess 81 or openings 96 adapted to receive a fastener 90, i.e., a staple 79 or pin 91. Col. 4, lines 29-32, 46-48, col. 5, lines 19-24. The fasteners 90 do not have lengths such that the stiffening ring 29 can be parachuted down the fasteners 90. Instead, the pins 91 are inserted through the patient's heart tissue and into the openings 96 until barbs 94 extend through the opening 96 and engage an upper surface 82 of the shoulder 57. Col. 5, lines 24-28.

Turning to the present claims, claim 1 recites a heart valve device for connection to a first mass that includes, *inter alia*, a gasket body comprising an annular wall defining a gasket radius around a longitudinal axis central to the gasket body, . . . the gasket body further comprising a sewing ring including a skirt extending radially outwardly from the first edge and a complementary attachment device, . . . wherein the complementary attachment element comprises a receptacle, the receptacle comprising a ratchet tooth for self-ratchetedly engaging a detent on an elongate attachment device received therethrough.

The Griffin et al. reference fails to disclose, teach, or suggest a receptacle that includes a ratchet tooth for self-ratchetedly engaging a detent on an elongate attachment device received therethrough. In contrast, at most, the Griffin et al. reference discloses a smooth-walled opening for receiving a pin with a barb that engages an upper surface of a shoulder once the pin is

inserted through the opening. Accordingly, claim 1 and its dependent claims are neither anticipated by nor otherwise obvious over the Griffin et al. reference.

The Peterson et al. reference also fails to teach or suggest a receptacle comprising a ratchet tooth for self-ratchetedly engaging a detent on an elongate attachment device received therethrough, as recited in claim 1. Instead, at most, the Peterson et al. reference merely discloses a plurality of smooth-walled apertures or holes 24 for sutures, pins, or other attachment apparatus. Paragraph 0032; FIGS. 4, 6, 7, 9, 10-13. Accordingly, claim 1 and its dependent claims are neither anticipated by nor otherwise obvious over the Peterson et al. reference.

Turning to claim 92, a heart valve device for connection to a first mass is recited that includes an annular body comprising a wall defining a circumference; a plurality of receptacles spaced apart around the circumference of the wall, each receptacle comprising an element defining a shelf and a slope; and a plurality of elongate attachment devices receivable through the receptacles, each attachment device comprising a detent for self-fixturingly ratcheting through a respective receptacle, the attachment devices having lengths such that, once the attachment devices are received through the receptacles, the annular body can be parachuted down the attachment devices.

First, the Griffin et al. reference fails to teach or suggest a receptacle that includes an element defining a slope and a shelf. Instead, at most, the Griffin et al. reference discloses smooth-walled opening for receiving a pin. Second, the Griffin et al. reference does not teach or suggest attachment devices having lengths such that, once the attachment devices are received through the receptacles, the annular body can be parachuted down the attachment devices. Instead, the Griffin et al. reference discloses a pin that is attached to tissue and then inserted

through the opening until a barb engages an upper surface of a shoulder. The Griffin et al. reinforcing ring cannot be parachuted down the pin, as claimed. Therefore, claim 92 and its dependent claims are neither anticipated by nor otherwise obvious over the Griffin et al. reference.

Finally, claim 108 also recites a plurality of elongate attachment devices receivable through respective fixturing devices, the attachment devices having lengths such that, once the attachment devices are received through the receptacles, the annular body can be parachuted down the attachment devices. Accordingly, for similar reasons to claim 92, claim 108 and its dependent claims are also neither anticipated by nor otherwise obvious over the Griffin et al. reference.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,

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